

REMARKS

Reconsideration and withdrawal of the rejections set forth in the Office Action dated June 16, 2006 are respectfully requested. A separate petition for a one-month extension of time is enclosed.

I. Amendments

Claim 19 is amended to recite that the solution is applied to the microprotrusions. Basis for omission of the language related to "only one or more of" the microprotrusions is found in the provisional priority application, 60/244,038, for example, on page 12, lines 12-22.

Claim 23 is amended to omit reference to analogs and salts. Basis for the omission is found in provisional priority application, 60/244,038, on at least page 14, lines 1-7.

Claim 28 is amended to omit reference to a "non-contiguous" pattern. Basis for the omission is found in the provisional priority application, 60/244,038, on page 10, lines 29-31.

Accordingly, the claim amendments add no new matter.

II. Double-Patenting Rejection

Claims 18-24, 28-35, and 47 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over pending claims 54-64 of copending application no. 11/034,891 ("891 application"). This rejection is respectfully traversed for the following reasons.

The Examiner maintains this rejection on the grounds that (i) it is not required for the instant claims to describe or suggest the limitations of the claims in the '891 application (Office action, page 3, lines 5-6) and (ii) removal of language directed to counter-ions from the '891 application is merely a broadening of the claim (Office action, page 3, lines 10-11).

With respect to (i), the Examiner is of the mind that the legal standard is that the '891 application "need only describe or suggest the limitations of the instant claims" (Office action, page 3, lines 5-8). Applicants remind the Examiner that the correct legal standard is whether the invention in the claims of the instant application would have been an obvious variation of the invention defined in the claims of the '891 application. In this analysis, the disclosure of the '891 application may not be used as prior art, but is looked to, by way of example, for an understanding of the meaning of the claims (M.P.E.P. § 804).

With this standard in mind, the question to be answered is "does any claim in the instant application define an invention that is merely an obvious variation of an invention claimed in the '891 application?". A key difference between the instant claims and claims 54-64 of the '891

application is the components in the drug formulation applied to the microprotrusion members. With this in mind, the question can be more specifically states as, "is the instant claim step related to applying a solution of an active agent to a microprotrusion member an obvious variation of the claims in the '891 application, which require the step of applying a solution containing an active agent, a non-volatile counterion, and a volatile counterion to a microprotrusion member?"

To arrive at the instant claim step of applying a solution containing an active agent from claims 54-56 of the '891 application, a skilled artisan would need to omit the non-volatile counterion and the volatile counterion from the drug formulation applied to the device in the '891 application. There is nothing in the claims of the '891 application to suggest to a skilled artisan omission of both of these components from the formulation. In fact, the presence of these counterions appears to be a critical feature of the claims in the '891 application, as the claims additionally state that the non-volatile counterion causes formation of a first species of the biologically active agent that has improved solubility and the volatile counterion causes formation of a second species of the biologically active agent that has reduced solubility when the formulation is dried.

With respect to (ii), and the Examiner's observation that removal of language directed to counter-ions from the '891 application is merely a broadening of the claim, Applicants note that this is not the legal standard. To arrive at the instant claims from a reading of, for example claim 64 of the '891 application, a person would need to omit the non-volatile counterion and the volatile counterion from the drug formulation. Nothing in the claims of the '891 application would suggest the desirability of omitting these components. In fact, to do so would appear to negate a critical aspect of the invention set forth in the claims of the '891 application. Omission of one or more elements that are key to a claim is not an obvious omission.

Moreover, the purpose of a double-patenting rejection is to prevent unjustified or improper extension of the right to exclude granted by a patent. On the facts here, the instant application is earlier-filed, with a priority date of October 26, 2000. The '891 application has a priority date of June 30, 2003. Thus, grant of the instant claims does not lead to an extension of the right to exclude the subject matter of the '891 claims, since the instant claims will expire several years before the expiration of any claims that may grant from the '891 application.

For these reasons, withdrawal of the provisional rejection for obviousness-type double patenting is respectfully requested.

III. Rejections under 35 U.S.C. § 102

Claims 1-15 and 20-21 were rejected under 35 U.S.C. §102(e) as being anticipated by Dalton, WO 02/07813. This rejection is respectfully traversed for the following reason.

Applicants' amendments to the claims bring the claim scope with the disclosure set forth in the priority application 60/244,038. Specifically, claims 19, 23, and 28 are amended as described in Section I above. Applicants note, however, that the claim language relating to "coating an agent onto the member" is supported by the priority application on at least page 15, lines 3-6. Further, use of an adjuvant in a coating solution that becomes a dried coating is supported by the priority application on at least page 14, lines 14-17.

Thus, the claims as amended are entitled to a priority claim of October 26, 2000, and Dalton, with an international filing date of July 18, 2001, is not prior art against the claims.

Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §102.

IV. Rejections under 35 U.S.C. § 103(a)

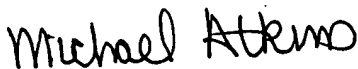
Claims 22-24 and 34-35 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Dalton. This rejection is respectfully traversed on the grounds that Dalton does not qualify under any subsection of 35 U.S.C. §102 as prior art, as discussed in the section above. Accordingly, withdrawal of the rejection under 35 U.S.C. § 103(a) is respectfully requested.

V. Conclusion

In view of the above amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Therefore, a Notice of Allowance is respectfully requested. If the Examiner believes a telephone conference would expedite the prosecution of the present application, the Examiner is encouraged to call the undersigned at (650) 564-5887.

Respectfully submitted,

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